



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/542,821

10/21/2005

Luis Octavio Guisasola

4258-113

8347

23448

7590

06/09/2009

INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

06/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/542,821 | Applicant(s) GUISASOLA ET AL. | |
| | Examiner Barbara P. Badio | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-15 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

2. The filing of a certified copy of the priority document is noted.

Claim Rejections - 35 USC § 101

3. The rejection of claim 11 under 35 101 is made moot by the cancellation of the instant claim.

Claim Rejections - 35 USC § 112

4. The rejection of claim 11 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claim.
5. The rejection of claim 12 under 35 USC 112, second paragraph is withdrawn.

Double Patenting

6. The rejection of claim 12 under 35 USC 101 over claim 25 of copending Application No. 10/542,580 is withdrawn.

Claim Rejections - 35 USC § 102

7. The rejection of claim 11 under 35 USC 102(b) over Kim et al. (WO 96/30390) is made moot by the cancellation of the instant claim.

8. The rejection of claims 1, 5, 8 and 9 under 35 USC 102(b) over Kim et al. (WO 96/30390) is maintained and claim 13 is rejected under 35 USC 102(b) over Kim et al. (WO 96/30390).

Applicant's argument is that the process and, thus, VA-2914 isopropanol hemisolvate are novel because the prior art teaches evaporation of the solvent not recrystallization. Applicant's argument was considered but not persuasive for the following reasons.

The skilled artisan in the art would be aware that crystals can be formed by evaporation of the solvent or cooling of the solvent. However, both the prior art and the instant claims encompass purification of VA 2914 via dissolution in isopropanol followed by removal of the solvent with the production of a solid which retains said isopropanol. Claim 8 is not limited in how the crystal is formed and, thus, is inclusive of the process taught by Kim. Additionally, the examiner notes that according to Example 2, the isopropanol hemisolvate obtained is a cake and not crystals.

For these reasons and those given in the previous Office, the rejection of claims 1, 5, 8 and 9 under 35 USC 102(b) over Kim et al. (WO 96/30390) is maintained and claim 13 is rejected under 35 USC 102(b) over Kim et al. (WO 96/30390).

Claim Rejections - 35 USC § 103

9. The rejection of claims 2-4, 6, 7, 10 and 12 under 35 USC 103(a) over Kim et al. (WO 96/30390) as applied to claims 1, 5, 8 and 9 above, and, further in view of Cook et al. (WO 99/45022) is maintained and claims 14 and 15 are rejected under 35 USC 103(a) over Kim et al. (WO 96/30390) as applied to claims 1, 5, 8 and 9 above, and, further in view of Cook et al. (WO 99/45022).

Applicant argues the final VA-2914 produced by the process of Kim is yellow which is indicative of the presence of impurities whereas the instant process results in the formation of white crystals. Additionally, applicant argues (a) the difference in the melting points of VA-2914 and (b) Cook does not disclose the claimed carbinol acetate. Applicant's argument was considered but not persuasive for the following.

As discussed above in #8, Kim teaches a process similar to that of the claimed invention. The fact that the isopropanol hemisolvate is produced by evaporation not cooling the solvent is not a patentable distinction since (a) crystals can be formed by either evaporating or cooling the solvent and (b) claim 8 is not limited to the formation of crystals via cooling. Applicant also argues the differences between the melting points, i.e., 189°C vs. 183-185°C and the color of the final VA-2914 as taught by the Kim. However, (a) the difference in the melting points noted by applicant is not significant and (b) because the process as taught by Kim is encompassed by the instant invention as discussed above in #8, the skilled artisan would have the reasonable expectation that the end product would also be similar.

Applicant seems to be arguing unexpected and unobvious results without a true side-by-side comparison. If, it is applicant's position that cooling to form the hemisolvate results in a solid that differ from the solid taught by Kim, a comparison of the processes wherein the only difference is the method via which the hemisolvate is obtained from the isopropanol is necessary.

Lastly, applicant argues Cook does not disclose the claimed carbinol acetate. The rejection made note that the claimed compound is encompassed by the genus taught by reference. Based on the teaching of the process exemplified and noted in the previous Office Action, Cook renders obvious the claimed carbinol acetate as well as the process of making the corresponding 4,9-diene derivative.

The recitation of ethanol/water and ethyl ether as solvent systems for crystallization of VA-2914 from the corresponding isopropanol hemisolvate in claim 14 is noted. As disclosed by the present specification, the use of said solvents systems in the crystallization of VA-2914 is known in the art (see page 8, lines 11-19) and, thus, the instant claim is prima facie obvious.

For these reasons and those given in the previous Office Action the rejection of claims 2-4, 6, 7, 10 and 12 under 35 USC 103(a) over Kim et al. (WO 96/30390) as applied to claims 1, 5, 8 and 9 above, and, further in view of Cook et al. (WO 99/45022) is maintained and claims 14 and 15 are rejected under 35 USC 103(a) over Kim et al. (WO 96/30390) as applied to claims 1, 5, 8 and 9 above, and, further in view of Cook et al. (WO 99/45022).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1612